REMARKS

In the Office Action dated March 1, 2004, the Examiner noted typographical errors in the equation in claim 18, which have been corrected. The equation in claim 18, as noted by the Examiner was intended to correspond to equation (22) in the substitute specification.

Applicants have also noted that the same equation appearing earlier in the substitute specification (Equation (3)) also contained typographical errors, which have been corrected.

Claims 10-16 were rejected under 35 U.S.C. §103(a) as being unpatentable over European Application 08 79 618 in view of Cooper. The Examiner stated the European Application discloses a pacemaker corresponding to the subject matter of claim 10, but stated that the European Application does not disclose limiting the pacing rate to a value that is below the initial onset of an ischemic condition, which the Examiner stated is the condition where energy supplied to the heart is less than the energy consumed. The Examiner stated the Cooper reference discloses a rate responsive pacemaker and includes a teaching that it is desirable to set the upper pacing rate at a value that is just below the onset of an ischemic condition.

Applicants believe that claims 10-16 as set forth in Amendment "A" Prior to Action are patentable over the teachings of the European Application and Cooper, and therefore the above rejection is respectfully traversed for the following reasons.

In the rate adaptive pacemaker set forth in independent claim 10, and the claims depending therefrom, the pacing rate is limited to an upper limit value that is set by determining a relation between the energy supplied to the myocardium and the energy consumed by the myocardium, so that the upward limit is set to always

maintain the energy supplied to the myocardium as exceeding the energy consumed by the myocardium.

The European Application is identified and discussed at page 1 of the present application, and Applicants acknowledged that this reference discloses a pacemaker wherein an upper pacing rate is decreased upon the detection of ischemia by an ischemia detector. The reason why the upper pacing rate is decreased under ischemic conditions is also explained in the introductory portion of the present specification. Normally a rate adapted pacemaker operates to continually increase the pacing rate as the patient's demand (activity) increases. The patient's activity level can be monitored in any of a number of known ways. An upper limit to the pacing rate is set, however, otherwise the pacing rate could reach a dangerously high level during high demand situations. It has been found that under ischemic conditions, it is desirable for physiological reasons to decrease this upper limit, compared to the upper limit that may be appropriate in the absence of ischemia.

The European Application discloses a number of different ways of monitoring for ischemic conditions, however, none of these monitoring techniques involves determining the energy supplied to the myocardium and the energy consumed by the myocardium, and setting the upper limit for the pacing rate dependent on a relationship between these energies. The European Application, at column 3, line 22 through column 1, describes a number of techniques for detecting ischemia, none of which involve determining the aforementioned relationship between energy supplied to and consumed by the myocardium.

The Cooper reference provides similar teachings, with the only difference being that two sensors are used to monitor the onset of ischemia, rather than a

single sensor as disclosed in the European Application. Nevertheless, all of the types of sensors that are disclosed for use in the Cooper reference are similar to or the same as the various types of sensors disclosed in the European Application. There is no teaching in the Cooper reference to monitor the energy supplied to and consumed by the myocardium as an indicator for ischemia, and therefore there is no teaching in that reference to set an upper pacing rate limit dependent on a relationship between the supplied and consumed energies. In the preferred embodiment, the Cooper reference teaches combining signals from an activity sensor and a metabolic sensor, which in the preferred embodiment is an impedance sensor, and the upper limit for the pacing rate is then set based on a mathematical combination, which varies under different conditions, of the signals from these two sensors. The reason for combining the signals in different ways in the Cooper reference is summarized at column 2, lines 52-63 thereof, wherein Cooper states that a patient's physical activity can be partitioned into five periods, each requiring different demands, and therefore the combiner circuit in the Cooper reference combines the signal from the activity sensor with the signal from the impedance sensor in different ways in the different respective periods.

Therefore, if the European Application were modified in accordance with the teachings of Cooper, this would not result in any "new" way of detecting ischemia, but would merely result in the dual sensors of Cooper and the combiner circuit of Cooper being used to detect ischemia, in place of the single ischemia detector disclosed in the European Application. As noted above, however, neither of those references discloses or suggests using a relationship between the energy supplied to and consumed by the myocardium as a basis for setting the upper pacing rate.

In substantiating the aforementioned rejection, the Examiner stated that an ischemic condition is the condition where energy supplied to the heart is less than the energy consumed. While this may be an accurate physiological statement, it is information that is nowhere present in the European Application or the Cooper reference, and the Examiner has only been able to learn this information from the present disclosure. As noted above, both the European Application and the Cooper reference disclose many ways of detecting ischemia, none of which involve monitoring energy consumption. Moreover, the present Applicants do not claim such energy monitoring as a basis for *detecting* ischemia, but only as a basis for determining the upper limit value. There may be more accurate or reliable ways to actually *detect* ischemia, but only the present Applicants have had the insight to use the relationship between energy supplied to the myocardium and energy consumed by the myocardium as a basis for setting the upper pacing limit in a rate adaptive pacemaker.

Since the only location where this information is found is the present disclosure, rather than the references relied upon by the Examiner, Applicants respectfully submit that the combination proposed by the Examiner, aside from that resulting in a pacemaker that would operate according to the subject matter of claim 10, has occurred to the Examiner only through hindsight after the Examiner has had the benefit of reading the present disclosure. No teaching on the above point is found in either of the references relied upon by the Examiner.

Moreover, Applicants do not agree with the Examiner's statement that Cooper discloses that it is desirable to set the upper pacing rate at a value that is just below the onset of an ischemic condition. The Examiner did not cite a specific passage in

the Cooper reference as allegedly providing such a teaching, however, in the copy of the Cooper reference provided with the Office Action, claim 9 thereof was highlighted. Claim 9 depends from claim 8 and states that the limiting means (of claim 8) limits the activity indicated rate signal to a value that is smaller than the maximum level. This does not support the Examiner's conclusion that the Cooper reference teaches setting the maximum rate at a level that is just below the onset of an ischemic condition. As noted above, the Cooper reference combines the respective signals from an activity sensor and a metabolic sensor in different ways under different conditions, and it is the result of this *combination*, rather than the individual activity signal or the individual metabolic signal, that determines the actual upper limit. In claim 8, it is stated that the limiting means limits the activity indicated rate signal to a preselected range dependent on the maximum level. Therefore, in claim 8 there is no preclusion of the "preselected range" including values that *exceed* the maximum level. As noted above, this does not mean that this will result in the pacing rate actually exceeding the maximum level, but refers only to the contribution that the activity signal will be permitted to make to the overall combination. Claim 9 referred to by the Examiner then further limits claim 8 by stating that the upper value of the aforementioned preselected range will be equal to the maximum level, thereby further limiting the contribution that the activity signal can make to the overall contribution. This is for the purpose of effectuating one of the "rules" that are described in the Cooper reference beginning at column 10, line 56 and continuing through column 11, line 37.

Therefore, not only does the Cooper reference fail to provide the teaching characterized by the Examiner, but also, when the Cooper reference is properly

analyzed, modification of the European reference in accordance with the teachings of the Cooper would not result in a rate responsive pacemaker as set forth in claims 10-16. None of claims 10-16, therefore, would have been obvious to a person of ordinary skill in the art based on the teachings of those references.

Applicants note with appreciation the Examiner's statement that claims 17-20 would be allowable if rewritten in independent form, however, in view of Applicants belief that claims 10-16 are patentable over the references relied upon by the Examiner, claims 17-20 have been retained in dependent form at this time.

All claims of the application are therefore submitted to be in condition for allowance, and early reconsideration of the application is respectfully requested.

Submitted by,

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